November 16, 2017

The Honorable Orrin Hatch
United States Senate
104 Hart Senate Office Building
Washington, DC 20510

The Honorable Sheldon Whitehouse
United States Senate
530 Hart Senate Office Building
Washington, DC 20510

RE: *Ensuring Patient Access and Effective Drug Enforcement Act of 2016*[1]

Dear Senators Hatch and Whitehouse,

We are deeply appreciative of your consistent concern and support for the health of Americans struggling with debilitating, painful diseases and conditions. We do not wish to return to the situation many of them faced prior to passage of the *Ensuring Patient Access and Effective Drug Enforcement Act of 2016:* seriously ill and, in some cases, dying Americans were suddenly unable to access prescribed and medically necessary treatment due to immediate shut downs of supply chain registrants such as distributors and pharmacies in the areas in which they lived.

From a survey of their membership in December 2013, the National Community Pharmacists Association (which then dispensed nearly 40% of all prescriptions) summarized that "many pharmacies are increasingly unable to procure controlled substances which is of great concern for patients who need these medications." Key highlights of the survey[2] included the following:

- Approximately 75% of respondents experienced three or more delays or issues caused by stopped shipments with their controlled substance orders, over the past 18 months.
- On average, 55 patients per pharmacy were impacted by these delays.
- 89% of impacted pharmacies received no advanced notice of the delay; they only found out when their order arrived and included just non-controlled substances.
- 60% said the delays in receiving these requested medications lasted at least one week.
- 67.9% were unable to procure controlled substances from an alternate source, such as a secondary wholesaler.
- Most reported having to turn patients away.

The survey included an open-ended comments section. One pharmacist wrote, "This situation has literally brought customers to tears in our store. I fully understand the diversion and abuse of these powerful chemicals. I agree that something must be done, but to deny pain management to deserving individuals is inhumane at best. We have to find a way to curb the abuse and still provide relief from pain for those truly suffering."

The *Ensuring Patient Access and Effective Drug Enforcement Act of 2016* (the "Act"), which you sponsored, received bipartisan, unanimous support of both houses of Congress and was signed into law by President Barack Obama on April 19, 2016.

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[1] https://www.congress.gov/114/plaws/publ145/PLAW-114publ145.pdf (accessed 11.1.2017).
[2] http://www.ncpanet.org/pdf/survey/2014/controlled-substances-access-survey.pdf (accessed 11.1.2017).

The law's passage came about because Congress was concerned about:

(1) Protecting legitimate patient access to prescription pain medication,

(2) The then-current law that gave the Drug Enforcement Administration (DEA) undefined discretion to immediately suspend a registration to distribute controlled substances without notice and without provision to inform the registrant of suspected violations while the agency investigated, and

(3) The lack of opportunity for corrective action in cases where the DEA determined a controlled substance was not properly being controlled.

On October 15, 2017, CBS's "60 Minutes" aired a program entitled "Ex-DEA agent: Opioid crisis fueled by drug industry and Congress."[3] The story relied on the one-sided claims by ex-DEA Deputy Assistant Administrator Joe Rannazzisi that the Act derails DEA's ability to pursue prescription opioid distributors. This is simply not true. DEA's authority to immediately suspend a registration is still preserved under this Act. The Act clarifies the DEA's authority by defining "imminent danger to the public"; it does not diminish that authority. A recent *Wall Street Journal* Editorial Board article succinctly articulated that this Act merely tweaked the threshold of one DEA tool and was intended to strike a better balance between enforcement and appropriate medical use.[4] Nevertheless, Senators Claire McCaskill (D-MO) and Joe Manchin (D-WV) introduced legislation to repeal the Act. As of the date of this letter, four additional bills have been filed for the same purpose.

Under the Act, which is now law, if the DEA suspects that an individual or entity registered to distribute or dispense controlled substances is not maintaining effective controls, the DEA is required to: (1) inform them that they are under investigation; (2) inform them what measures they are suspected of violating; and (3) provide them 30 days to correct the situation. The Act additionally authorizes the DEA to bypass this notification process and immediately suspend a registration in cases where "there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration."[5]

In its June 2015 report, the U.S. Government Accountability Office started with this statement: "The CSA was enacted in 1970 to regulate and facilitate the use of controlled substances, including certain prescription drugs such as opioid pain relievers, for legitimate medical, scientific, research, and industrial purposes while preventing them from being diverted for illegal uses. DEA's Office of Diversion Control is responsible for administering and enforcing the provisions of the CSA as they pertain to *ensuring the availability of controlled substances for legitimate uses while limiting their availability for abuse and diversion*."[6] (emphasis added)

On two occasions, Jan Chambers, President of the National Fibromyalgia & Chronic Pain Association, one of the undersigned organizations, publically asked Mr. Rannazzisi to acknowledge that there are

[3] https://www.cbsnews.com/news/ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/ (accessed 11.1.2017).
[4] A Bipartisan Drug Cartel? https://www.wsj.com/articles/a-bipartisan-drug-cartel-1508886015 (accessed 11.1.2017).
[5] https://www.congress.gov/114/plaws/publ145/PLAW-114publ145.pdf/ (accessed 11.5.17).
[6] https://www.gao.gov/assets/680/671032.pdf (accessed 11.1.2017).

thousands of Americans with severe pain who need access to prescription medication, including prescription opioids, as part of an overall pain management plan. Mr. Rannazzisi told Ms. Chambers that he wasn't concerned and didn't care about these individuals--that his job was enforcement. He further told Ms. Chambers that she should contact the parents of children who had died from an opioid overdose and listen to them about why there should not be prescription opioids in America.

Contrary to Mr. Rannazzisi's callous reply, *all* of us care about people who have died from prescription and illicit opioid overdoses. These are tragedies that no one wants to see continue. We also care about suicides due to unrelieved pain and the unnecessary suffering of patients in pain at the end of life or dealing with severely painful chronic conditions. Patients with chronic pain are twice as likely to attempt suicide compared with those without chronic pain, an action generally caused by a myriad of associated psychological, physical, and social factors.[7]

We all want registrants that have engaged in illegal activities to be dealt with appropriately—and even shut down in cases where there is imminent danger to the public--but we also want to be certain that innocent Americans struggling with debilitating chronic conditions do not have their access to treatment suddenly cut off. Unless and until new and effective non-addictive pain medications become available or patients have access to effective non-pharmacological treatments, eliminating access to appropriately prescribed opioid medications for severe pain is inhumane.

The last provision in the law requires a report back from Health and Human Services to Congress within one year, including obstacles to legitimate patient access to controlled substances. The report calls for feedback and recommendations from a committee to include patient representatives.

We urge Congress not to allow Mr. Rannazzisi's one-sided presentation to defeat a law that provides essential protections for many of the most vulnerable in our country. Chronic pain patients often suffer in silence. Rarely do they win the attention of multi-million-dollar news programs eager to portray them as heroes. But they do, nonetheless, deserve Congress's consideration.

The simple fact is that unchecked DEA authority can result in profound consequences for chronic pain sufferers. A balance is needed to ensure that patients have access to the life-saving—and life-improving—medication they need while preserving DEA's authority to go after the truly bad actors. The *Ensuring Patient Access and Effective Drug Enforcement Act of 2016* is a reasonable approach that strikes that balance. Congress should keep the law in place to help protect patients with severe pain.

We want to again thank you for courageously speaking out for the needs of so many Americans who are often too ill and disempowered to speak for themselves. We invite the opportunity to respond to concerns or answer questions. Please contact Jan Chambers at National Fibromyalgia & Chronic Pain Association (jan.f.chambers@gmail.com).

Respectfully yours,

Academy of Integrative Pain Management

Alliance for Balanced Pain Management

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3942549/ (accessed 11.1.2017.

Alliance for the Treatment of Intractable Pain

American Society for Pain Management Nursing

Chicagoland Fibromyalgia & Chronic Pain Organization

Chronic Pain Research Alliance

Conquering Chronic Pain Together Support Group

Ehlers Danlos Society

Families for Intractable Pain Relief

FibroAcademy

Fibromyalgia Association of Michigan

Fibromyalgia Fight Club of Northern Virginia

Fibromyalgia Pathways

Fibromyalgia Warriors Living Life

Florida Fibromyalgia & Chronic Pain Network

Florida Fight for Pain Care Action Network

For Grace

Hereditary Neuropathy Foundation

International Fibromyalgia Coaching Institute, LLC

International Pain Foundation

Leaders Against Pain Action Network

National Community Pharmacists Association

National Fibromyalgia & Chronic Pain Association

North Carolina Together Walks

Reflex Sympathetic Dystrophy Syndrome Association

Richmond Fibromyalgia & Chronic Pain Organization

Sherri Little Foundation, Inc.

Tennessee Pain Care for All

The Pain Community

TMJ Association

U.S. Pain Foundation

Attachment: WSJ Editorial Board article

cc:

The Honorable Mitch McConnell
Majority Leader of the Senate
317 Russell Senate Office Building
Washington, DC 20510

The Honorable Chuck Schumer
Minority Leader of the Senate
322 Hart Senate Office Building
Washington, DC 20510

The Honorable Chuck Grassley
Chairman, Senate Committee on the Judiciary
135 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Dianne Feinstein
Ranking Member, Senate Committee on the Judiciary
331 Hart Senate Office Building
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